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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,637	JEHANLI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed December 24, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 1-16 and 18-21 have been amended. Claims 1-16 and 18-21 are under consideration in the office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1-3, 5-10, 12 and 14-21 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) and Baker et al., in view of Cole et al., (US Patent 4,589,612);

b) The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996), Baker et al., and Cole et al., (US Patent 4,589,612) further in view of de Jaeger et al., (US Patent 4,837,168); and

c) The rejection of claims 11 and 13 under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) Baker et al., and Cole et al., (US Patent 4,589,612) in further view of Esser.

Response to Arguments

3. Applicant's arguments filed December 24, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 11 and13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. The rejection was on the grounds that the claim scope is uncertain since the trademark NUNC-IMMUNO™ STICK cannot be used properly to identify any particular material or product. Applicants assert that because the shape of the NUNC-IMMUNO™ STICK is well known it satisfies the requirement under 35 U.S.C. 112, second paragraph.

However, as previously stated a trademark is used to identify a source of goods, and not the goods themselves. Thus, a trademark does not describe the goods associated with the trademark. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion. The very fact that a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, means that the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark

would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Applicants assert that the presence of the trademark describes the shape and material to which the claims are drawn, therefore the use of the trademark clearly acts to describe the particular material or product shape. Therefore, the claim scope is uncertain and the use of the trademark constitutes an improper use, therefore, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-16 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to the antibody being labeled with "gold material latex particles or both." It is unclear how the label is gold material latex particles. Normally, labels are either gold material specifically colloidal gold particles

or latex particles specifically latex colored particles. A label is not gold material latex particles. Furthermore, the claim refers to "both", it is unclear what the "both" is referring to when only one label has been disclosed. Therefore, the claim is unclear and the metes and bounds of the claims are unclear and clarification is requested.

6. Claims 2-3, 6, 8, 10, 12, 15 and 21 recite alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 5-7, 9-10,12, 14-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) in view of Cole et al., (US Patent 4,589,612).

The claims are drawn to a medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid.

Jehanli et al., (1996) teach determination of Captopril in human blood by an ELISA assay. Captopril is an orally active Angiotension-Converting Enzyme (ACE) inhibitor used for treatment of hypertension and congestive heart failure (page 914). The quantitation of captopril in biological fluids has been carried out previously in the art, however the author describes the development of a sensitive, simple and rapid competitive ELISA assay for the determination of captopril (page 914). Captopril, the drug was covalently linked to bovine serum albumin (page 914). Antibodies were created from the immunization protocol (page 915). Thus making a drug conjugate as described by the claims to be between a drug and a protein. Preparation of rabbit serum albumin (RSA)-captopril conjugate for the immunoassay was disclosed again teaches a drug conjugate (page 915). Figure 1 shows chemical coupling of captopril to both bovine serum albumin and rabbit serum albumin. The microtiter plate immunoassay consisted of coupling captopril to RSA using well-known general procedures already described (page 915). The microtitre strips were coated by incubation with the RSA-captopril (page 915). Thus, this first part is a coated stick having the required shape with the drug conjugate, rabbit serum albumin. Anti-captopril antibody was added to the tube shaped wells and strips (page 915). Thus, this second part contains labeled antibody and is adapted for receiving the biological fluid. The strips were incubated for one hour at ambient temperatures and the washed bound antibody was revealed (page

915). Color development was terminated after 30 minutes and the absorbance was determined (page 915). Human plasma samples containing various concentrations of captopril were tested and amounts of captopril were qualitatively or quantitatively determined (page 915). Maximum absorbance values and concentration of captopril in test samples was determined. Jehanli et al., teach both the medical kit and methods of using the kit to determine the presence of a drug. Jehanli et al., teach a medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first stick shaped part coated with a drug conjugate (albumin (RSA)-captopril conjugate) and a second tube-shaped part that contains a labeled antibody and is adapted for receiving biological fluid such as plasma wherein the first and second parts are in contact for 1 hour to indict by color change the drug activity. However Jehanli et al., do not teach an antibody labeled with gold material.

Cole et al., (US Patent 4,589,612) teach immunoassays can utilize a labeled component comprising a metal containing particle of a particular size and character to facilitate the maintenance of a generally stable, monodispersed suspension of the labeled component that was mixed and brought into contact with the sample to be analyzed (col. 4-5 lines 60-5). The labeled component can be an antibody labeled with metal particles such as gold sol particles which have been known in the art since 1975. Gold particles coated with antibody are intensely colored orange, red or violet depending on particle size (col. 6-7 lines 60-2). The gold labeled antibodies can be directly visualized with the naked eye (col. 7 lines 8-11). Metal sol assays require fewer steps and fewer reagents and are considered more stable than most enzyme labeled

antibodies (col. 7 lines 13-16). The particles can be used with either monoclonal or polyclonal antibodies (col. 8 lines 12-13). Moreover, such immunoassays can be used to detect controlled substances and other such small molecules (col. 9 lines 1-3).

It would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains an enzyme labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., wherein no more than routine skill would have been required to incorporate the gold labeled antibody of Cole et al. One would have a reasonable expectation of success by incorporating an antibody labeled with gold material, into the device and method of Jehanli et al., who already teach using the labeled antibodies to qualitatively or quantitatively determine the presence of a drug in a biological fluid. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent labeled antibody in the medical kit and method of determination as taught by Jehanli et al., since only the expected results would have been obtained. A skilled artisan would have had a reasonable expectation of success in switching the antibody labels when the prior art teaches that metal sols require fewer steps and reagents and are considered more stable than most enzyme labeled antibodies. Thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the gold labeled antibody ability to be linked with either monoclonal or polyclonal antibodies, its ability to be directly visualized, and that such labeled antibodies are known to used in immunoassays to detect drugs.

Applicants assert that the assay of Jehanli et al., took four hours of completion while applicants claim that their system provides results within 5 to 60 minutes. However applicants are comparing two different standards. Applicants predetermined time period claims are only drawn to the time when the first part is brought into contact with the second part wherein the predetermined time period is within 60 minutes. However applicants 4 hour time period refers to Jehanli et al., total time including preparation of the microstrips; coating of the tube-shaped second parts; and antibody preparation. Moreover, Jehanli et al., teaches that color development takes about 30 minutes, which is within the claimed range. Therefore applicants' arguments are not persuasive.

Applicants assert that Jehanli et al., requires several technical wash steps and equipment unlike the instant claims. However the claim language recites "comprising." The transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Therefore applicants' argument that Jehanli et al., is not obvious because it discloses a system with different

steps is not persuasive since Jehanli et al., teach a system with the same components and the rejection is maintained.

Applicants' assert that Jehanli et al., teach away from the claimed kit and method because it is less amendable to day-to-day conditions encountered with use by a hospital. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

It is noted that the use of references is not limited to what the authors describe as their own inventions or to the problems with which they are concerned. They are part of

the literature of the art, relevant for all they contain. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., and Cole et al., as applied to claims 1-3 and 5-7 above, and further in view of Baker et al. Jehanli et al., and Cole et al., have been discussed above however, neither teaches the use of Lisinopril.

Baker et al., teach antibodies to cardiac hypertrophy factors and uses. Baker et al., teach that ACE inhibitors refer to angiotension-converting enzyme inhibiting drugs which prevent the conversion of angiotension I to angiotension II (col. 15 lines 47-50). The ACE inhibitors may be beneficial in congestive heart failure by reducing systemic vascular resistance and relieving circulatory congestion (col. 15 lines 50-53). ACE inhibitors that both prevent the conversion of angiotension I to angiotension II include the drugs known as captopril and lisinopril (col. 15 lines 55-57). Thereby Baker et al., teach that captopril and lisinopril are with the same class of ACE inhibitors.

It would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated

with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli and Cole et al., wherein no more than routine skill would have been required to incorporate the lisinopril drug conjugate an of Baker et al. One would have a reasonable expectation of success by incorporating the ACE drug lisinopril, when the prior art already teaches the determination of another ACE related drug which has similar functions into the device and method of Jehanli et al., and Cole et al., who already teach using the labeled antibodies to qualitatively or quantitatively determine the presence of a drug in a biological fluid. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent drug and labeled antibody in the medical kit and method of determination as taught by Jehanli et al., and Cole et al., since only the expected results would have been obtained. Baker et al., clearly teaches that antibodies for the drugs are known in the art. Thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the need to determine the presence of the drug and the availability of drugs, drug conjugates and associated antibodies. A skilled artisan would have had a reasonable expectation of success in switching the ACE inhibitor drugs where the prior art already using one ACE drug can be detected and similar drugs are readily available.

Applicants urge that one skilled in the art would not have motivated to exchange the ACE inhibitor of lisinopril for the ACE inhibitor captopril. Applicants' assert that drug structure can differ dramatically between classes of ACE inhibitors, however applicants do not state that lisinopril and captopril have different drug structures. Neither do

applicants' state that lisinopril and captopril are in different drug classes. Thus, applicants; arguments are not persuasive. Applicants' assert that Baker et al., does not disclose that the drugs interchangeable, thus the interchange is not taught or suggested. However, the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Moreover, the essential objective inquiry is: "Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,* 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997). In determining equivalence, "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute plays a role substantially different from the claimed element." 41 USPQ2d at 1875. In this case, both lisinopril and captopril are ACE inhibitors; both block an enzyme in the body that is necessary to produce a substance that causes blood vessels to tighten, as a result, they relax blood vessels which lowers blood pressure and increases the supply of blood and oxygen to the heart (i.e., they both work by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and are generally taken orally). There is no evidence of record that the drugs

are not functional equivalents and could not be interchanged to allow one of skill in the art to determine their presence. Therefore applicants' arguments are not persuasive and the rejection is maintained.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996), and Cole et al., (US Patent 4,589,612) as applied to claim 1 above, and further in view of de Jaeger et al., (US Patent 4,837,168).

The claim is drawn to a medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a conjugated drug, and a second part that contains an antibody with colored latex particles and is adapted for receiving said fluid. The prior art has been discussed above, however none teaches using colored latex particles.

de Jaeger et al., teach a method of qualitatively or quantitatively determining a component of a complex formed between at least one specific binding agent and its corresponding bindable substance (col. lines 20-24). The color signal may be easily detected and optionally quantified either directly or if necessary after development (col. 2 lines 40-43). The optical properties of latex particles especially their color characteristics make them optimal labels (col. 2 lines 50-56). Examples of colored or colorable latex particles are well known in the art (col. 3-5 lines 10-40). Example 1 teaches the preparation of latex bound antibodies, performance of coupled latex wherein nitrocellulose strips were incubated with latex suspensions and color was then

developed (col. 17-18 lines 62-68). The detection sensitivity and specificity was determined along with designing a dipstick, see example 2.

It would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., and Cole et al., to include the colored latex particle label as taught by de Jaeger et al. One would have a reasonable expectation of success by incorporating the antibody labeled with latex colored particles, into the device of Jehanli et al., and Cole et al., who already teach using the labeled antibodies to qualitatively or quantitatively determine the presence of a drug in a biological fluid.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking the de Jaeger et al., reference individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to use an alternative yet functionally equivalent labeled antibody in the medical kit as taught by Jehanli et al., and Cole et al., since only the expected results would have been obtained; thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on colored latex particle labeled antibodies being known to be capable of direct visualization and useable in dipstick immunoassay supports to qualitatively or quantitatively determine the presence of an antigen.

10. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehanli et al., (1996) and Cole et al., (US Patent 4,589,612) as applied to claims 1, 10 and 12 above, and further in view of Esser. The prior art has been discussed above, however none teaches using the NUNC-IMMUNO ™ STICK.

The claims drawn to a medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate that has the shape and material of a NUNC-IMMUNO ™ STICK and a second part that contains a labeled anti-body and is adapted for receiving said fluid.

Esser teaches NUNC-IMMUNO ™ STICK. The immunosticks can be used for assaying one or two analytes with controls at the same time and can be used in the doctor's office or in the field. Assays testing one analyte use rabbit immunoglobulin IgG in a double antibody sandwich assay using anti-rabbit antibodies conjugated with

alkaline phosphatase (page 4). MaxiSorp sticks were coated with labeled antibody, alkaline phosphatase conjugated swine anti-rabbit antibodies (page 4). See Figure 1 wherein the immunostick ELISA of the analyte was performed. The NUNC-IMMUNO ™ STICK test systems consist of a tube and stick with a paddle.

It would have been prima facie obvious to modify the medical kit for qualitative or quantitative determination of a drug in a biological fluid comprising a first part coated with a drug conjugate and a second part that contains a labeled antibody and is adapted for receiving said fluid as taught by Jehanli et al., and Cole et al., to further incorporate the shape and material used in NUNC-IMMUNO ™ STICK test system. One would have a reasonable expectation of success by incorporating the NUNC-IMMUNO ™ STICK test system because it can assay multiple anaytes wherein both positive and negative controls are run at the same time on one immunostick and can be used in a doctor's office.

It is noted that applicant now argues that NUNC-IMMUNO ™ STICK disclosure is different than the instant claims because it uses enzyme labels; however this is contrary to applicants' earlier argument that NUNC-IMMUNO ™ STICK only refers to shape and material. Thus, applicants' arguments are inconsistent. Esser teaches the same shape and material as disclosed by the instant claims and applicants' arguments are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to use an alternative yet functionally equivalent immunostick as compared to the immunostrips as taught by Jehanli et al., and Cole et al., since only the expected results would have been obtained; thus the use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the ease and commercial availability of the NUNC-IMMUNO ^{TM} STICK test system.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 26, 2004

NITA MINNIFIELD
PRIMARY EXAMINER
3/31/04